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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/591,531 | 09/01/2006 | Frank Pflucker | MERCK-3223 | 2971 |
| 23599 | 7590 | 09/26/2008 | | |
| MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201 | | | EXAMINER | |
| | | | SULLIVAN, DANIELLE D | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/591,531 | Applicant(s) PFLUCKER ET AL. |
| | Examiner DANIELLE SULLIVAN | Art Unit 1616 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(o).

Status

- 1) Responsive to communication(s) filed on 01 September 2006.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-27 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-27 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>09/01/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-27 are pending examination on the merits. A preliminary amendment was received on 9/01/2008.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

The information disclosure statement filed 09/01/2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The term "emulsifier-free emulsion" is not disclosed in the specification.

Claim Objections

Claims 2-10, 13-16 and 18-27 are objected to because of the following informalities: "Characterised" should be replaced with "characterized" or the term "wherein"; "Photostabilisers" should be spelled "photostabilizers" in claims 8, 22 and 23; "Proces s" should be "process" in claim 16; "Comp osition" should be "composition" in claim 18. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 26 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession

of the claimed invention. The emulsifier-free emulsion is not disclosed within the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5, 6, 25 and 26 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5 and 6 recite the limitation "the walls of the capsules" in reference to an encapsulated organic UV filters. There is insufficient antecedent basis for this limitation in the claim.

Regarding claim 25, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 26 recites the limitation "emulsifier-free emulsion" in reference to an emulsion. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20, 22 and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heger et al. (US 2003/0143166).

Applicant's Invention

Applicant claims UV filters in powder form, obtained by spray-drying or freeze-drying a dispersion. Applicants also claim a process of preparing the UV filters and compositions comprising the UV filters. Claim 2 limits the dispersion to being aqueous. Claims 3, 4, 11 and 12 limit the UV filters to being encapsulated and organic. Claims 7, 8, 20-21 and 25 further comprise photostabilizers, cosmetics oils and/or antioxidants. Claims 20 and 24 further comprise an additional UV filter selected from octyl methoxycinnamate. Claim 15 specifies that the process may introduce additives before or during the process. Claim 23 limits the size to 10nm to 100nm.

Determination of the scope and the content of the prior art

(MPEP 2141.01)

Heger et al. teaches aqueous dispersions of organic UV filters, which may be encapsulated (abstract; [0015]). In the process for preparing the dispersions the antioxidants and oils (additives) are added before and during the preparation of the dispersion phase [0106]-[1112]. Afterwards, the UV filters are spray-dried or freeze-dried to obtain a powder [0126]. The formulation may include antioxidants and light stabilizing agents (photostabilizers) to protect the UV filters [0039]. The dispersion preferably has a diameter of less than 500 um [0136]. Several examples include the additional

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Heger et al. does not give an example of the invention that is obtained by spray drying or freeze drying. However, it is clear that it is implied in order to convert the UV filter to a powder form the process requires the UV filters to be spray dried or freeze dried.

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Heger et al. to utilize UV filter obtained by spray drying or freeze drying. One would have been motivated to utilize the filter by the process of spray drying or freeze drying because Heger et al. teaches that doing so provided UV filters in powder form.

Claims 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heger et al. (US 2003/0143166) in view of Herzog (US 2003/0235540).

Applicant's Invention

Applicant claims the composition as disclosed above with a self-tanning agent.

Determination of the scope and the content of the prior art

(MPEP 2141.01)

The teachings of Heger et al. are disclosed above.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Heger et al. does not teach the addition of a self-tanning agent. It is for this reason that Herzog is joined.

Herzog teaches that encapsulated UV filters that may include dihydroxyacetone and erythrulose (self-tanning agents) [0003], [0142] and [0205]. The preparations are for cosmetic use may be formulated as skin-tanning preparations [0213].

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Heger et al. and Herzog to utilize a self-tanning agent. One would have been motivated to utilize a self-tanning agent because Herzog teaches that encapsulated UV filters including dihydroxyacetone and erythrulose may be used to obtain self-tanning formulations.

Claims 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heger et al. (US 2003/0143166) in view of Chaudhuri (WO 03/007906).

Applicant's Invention

Applicant claims the composition as disclosed above with at photostabilizer of formula V.

Determination of the scope and the content of the prior art
(MPEP 2141.01)

The teachings of Heger et al. are disclosed above.

Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)

Heger et al. does not teach the specific photostabilizer of formula V. It is for this reason that Chaudhuri is joined.

Chaudhuri teaches formula V as a photostabilizer which exhibits antioxidant properties (page 2, lines 25-35).

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Heger et al. and Chaudhuri to utilize the specific photostabilizer of formula V. One would have been motivated to utilize the photostabilizer because Chaudhuri teaches the formula is a photostabilizer which exhibits antioxidant properties.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danielle Sullivan whose telephone number is (571) 270-3285. The examiner can normally be reached on 7:30 AM - 5:00 PM Mon-Thur EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Danielle Sullivan
Patent Examiner
Art Unit 1616

/Mina Haghigian/
Primary Examiner, Art Unit 1616